

Study Protocol

Official Title: Sleep Promotion Program Primary Care (SPP PC) Open Trial

ClinicalTrials.gov ID (NCT number): NCT06239792; STUDY23010211 (Open)

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Scientific Background:

Adolescent depression is highly prevalent, impairing, costly, and associated with risk of suicide. Though universal screening for adolescent depression is recommended in pediatric primary care, primary care providers report limited time and few resources to manage mental health concerns in that setting. Short sleep duration and sleep-wake irregularity are consistently and significantly associated with adolescent depression and are considered key mechanisms of disease; thus, these sleep parameters are critical intervention targets for depressed youth. Efficacious behavioral strategies for disturbed adolescent sleep and daily rhythms lead to improved sleep *and* depression. However, little work has translated what is efficacious in a research environment for use in pediatric primary care, nor tested it in that setting. We developed a brief, scalable, behavioral Sleep Promotion Program (SPP) for adolescents with short sleep duration and sleep-wake irregularity, which relies on one individual session and smartphone technology to deliver evidence-based strategies. The SPP was tested among typically developing adolescents with short sleep duration and irregular sleep timing, showing good feasibility, acceptability, and greater improvements in total sleep time as compared to a wait-list control. Subsequently, we conducted qualitative interviews with young people interested in discussing the sleep of depressed adolescents to inform the translation of the existing SPP to be suitable for depressed adolescents.

Study Objectives: The current trial reports on the initial feasibility and effectiveness testing of the adapted SPP. We conducted an open trial (n=8) to iteratively refine the SPP program and implementation, per participant and staff feedback. We aimed to report on the feasibility, acceptability, and appropriateness of the adapted SPP, as well as change in depression score (PHQ-M) from screening to post-intervention, and improvement and/or worsening in sleep, psychiatric symptoms, and overall health via the clinical global impressions scale – improvement (CGI-I).

Study Design & Methods: This study includes an open pilot trial of a sleep promotion program (SPP). We partnered with a pediatrics practice in Western Pennsylvania (three office locations). All participants were recruited from this practice, and embedded social workers delivered the SPP sessions. University of Pittsburgh staff completed research procedures.

Potential participants were referred to the study by practice staff, or they could self-refer by responding to a flyer or text/email blast about the study. The University of Pittsburgh team conducted brief pre-consent/assent screening, and consented adolescents and their parent/caregiver who demonstrated initial eligibility. After obtaining informed assent/consent, staff conducted post-consent screening, which included questionnaires (adolescent and parent/caregiver) and a clinical interview (adolescent only). Consented participants were then shown a 2-minute psychoeducation video about sleep. Enrolled

participants completed a baseline visit, which included additional questionnaires (adolescent and parent/caregiver) and completion of a daily sleep diary simultaneous to wearing an actiwatch rest-activity monitor (adolescent only).

All participants in this open trial received SPP, which includes 2 face-to-face visits with a clinician, with automated smartphone technology during and for the month after these sessions. Sessions focus on the nature of the youth's sleep, strategies for improving sleep, and building motivation for change. Sessions could be completed in person or via videoconference or phone. The remainder of the program is delivered via automated smartphone technology between sessions and in the month after the second session. Weekly, adolescents are shown a summary of their sleep, based on sleep diary responses, with follow-up prompts about their intention to change their sleep.

All participants completed a follow-up assessment after the end of the treatment period, which repeated screening and baseline measures. At post-intervention, adolescents and parents also reported on the acceptability, appropriateness, and feasibility of the SPP program using the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure (FIM).

The primary sleep outcome measure is improvement in overall sleep (Clinical Global Impressions Scale – Improvement; CGI-I). Other primary outcomes include improvement depressive symptoms (PHQ-9-M).

Eligibility Criteria

To be included, youth must have the following:

- be ages 12-18 and able/willing to provide informed assent with consent from parent/guardian
- youth must currently be a patient at KPP who is currently depressed (on the Patient Health Questionnaire Modified for Teens (PHQ-9-M) score of 10 or above)
- youth must report a short sleep duration of less than 7 hours on school nights and/or a difference of greater than or equal to 2 hours weekday-weekend sleep timing
- youth must be a middle or high-school student

Parents must be age 18 or older and the parent/guardian of an enrolled youth participant and must have at least 10 hours face-to-face interaction with the youth participant per week.

Youth will be excluded if they:

- Have significant or unstable medical conditions;
- Have sleep apnea, narcolepsy, restless leg syndrome, nightmare disorder, or periodic limb movement disorder;
- Have a diagnosis of PTSD, bipolar disorder, psychotic disorder, or a substance use disorder;
- Are currently engaged in a cognitive or behavioral therapy for sleep improvement (such

as CBTI, IPSRT, or other);

- Have had changes to their medications that impact sleep in the month prior to screening;

- Express active suicidality that requires immediate treatment;

- Are unable or unwilling to comply with study procedures; OR

- Have any physical or mental condition that would preclude study participation.

Parents will be excluded if they:

- Express active suicidality that requires immediate treatment;

- Have any physical or mental condition that would preclude study participation; OR

- Are unable or unwilling to comply with study procedures.